

# **Not either/or: Beyond the Research/QI Dichotomy**

## **Protecting People While Increasing Knowledge: Ethics in Health Research, Evaluation and Quality Improvement**

Calgary, May 4-6 2008

Sarah Bowen, PhD, Director, Research and Evaluation  
Winnipeg Regional Health Authority



Winnipeg Regional  
Health Authority  
*Caring for Health*

Office régional de la  
santé de Winnipeg

*À l'écoute de notre santé*

# Perspective

- Researcher – evaluation, KT, qualitative
- Director of “embedded” research unit
- Member of WRHA Research Review Committee



# Context

- Growing recognition of need to differentiate between QI & research
  - # of guides to differentiate, suggested criteria
- BUT often assume quantitative, medical paradigm
  - What about
    - Qualitative HSR, particularly PAR?
    - Research *on* collaboration, KT?
    - Evaluation research?



# Case studies

- Evaluation of a demonstration project defined as non-research even though the design unique, potential new knowledge
- Tri-council funding not released until REB review, but PAR, KT research must work with community to identify proposal
- Engineering project to improve surgical flow & KT research projects denied because not intent for individual written consent from all observed
- Qualitative/KT research proposed as expedited because “low risk”.

# Compare 5 “types” of research/QI

- Traditional bio-medical
- Secondary data analysis
- Qualitative research (includes PAR)
- Evaluation research
- Knowledge translation research



# Assess according to commonly used research/QI criteria:

- Major Goal
- Major Focus
- Generalizable/transferable results?
- Clear protocol?
- Testable hypothesis?
- Funded by research funding body?



# Criteria continued..

- Using well recognized quantitative methods
- Using well recognized qualitative methods
- Individual consent required
- Knowledge of benefits
- Urgency of dissemination
- Expectation of use of results
- Additional burden to clients



**GOAL**

**FOCUS**

	<b>QI</b>	<b>Quant medical research</b>	<b>Secondary Analysis</b>	<b>Qualitative Research</b>	<b>Evaluation Research</b>	<b>KT Research</b>
<b>GOAL</b>	Improve care	New knowledge	New knowledge	New knowledge	New knowledge, also improved care, services	New knowledge, improved dissemination, collaborations
<b>FOCUS</b>	Clinical	Often clinical, may be community or HSR	Community Clinical or HSR	Community, Clinical or HSR	Often HSR, may be clinical, community	All

	Quant medical research	Secondary Analysis	Qualitative Research	Evaluation Research	KT Research
<b>Generalizable?</b>	Yes	Yes	Often transferable	Often	Often
<b>Clear Protocol?</b>	Yes	Yes	Sometimes, often flexible.	Often flexible	Sometimes, often flexible
<b>Testable Hypothesis?</b>	Yes, usually. May also be descriptive (e.g. CHA)	Often, but may be descriptive only	No	No	Potentially, but not usually

QI

Quant  
medical  
research

Secondary  
Analysis

Qualitative  
Research

Evaluation  
Research

KT  
Research

Potentially

Yes

Yes

Often  
transferable

Often

Often

Flexible

Yes

Yes

Sometimes,  
often  
flexible.

Often  
flexible

Sometimes,  
often  
flexible

Potentially  
but not  
usually

Yes,  
usually.  
May also  
be  
descriptive  
(e.g. CHA)

Often, but  
may be  
descriptive  
only

No

No

Potentially,  
but not  
usually

	Quant medical research	Secondary Analysis	Qualitative Research	Evaluation Research	KT research
<b>QI</b>					
<b>Funding?</b>	Usually	Usually	Usually	Sometimes	Often
<b>Quant methods?</b>	Yes	Yes	No	Often	Rarely
<b>Qual methods?</b>	No	Not usually	Yes	Often	Usually
<b>Consent?</b>	Yes	No	Usually (not for some observation studies, public record)	Depends, yes for evaluation research	Varied

QI	Quant medical research	Secondary Analysis	Qualitative Research	Evaluation Research	KT research
Yes, but not contextual evidence	Unknown	Unknown	N/A	Like QI – context unknown	May be unknown N.A some
Time-liness critical	Sometimes (e.g. SARS)	Not urgent	Not urgent	Timeliness important sometimes critical	Not usually
Use directly & immediately	No	No	No	Timely to improve services or make decisions.	Yes, both local and broader

**Known Benefits**

**Urgency of dissemination**

**Expected use of results**

# Case study 1

- Evaluation of a demonstration project defined as non-research even though the design unique, transferability of results
- **Issues:**
  - QI or research?
  - How NB is external funding?
- **Potential solutions:**
  - Clearer differentiation between *program evaluation* and *evaluation research*
  - Separation into research and evaluation components



# Case study 2

- Tri-council funding cannot be released until REB review, but PAR, KT research must work with community to identify proposal
- **Issues:**
  - Where does research start?
    - vicious circle – need \$ to do work, need work to get \$\$
  - Can prevent true participation
- **Potential solution:** 2 stage submission



# Case studies 3 & 4

- An engineering project to improve surgical flow denied because not intent to ask for individual consent from all patients/staff who might be observed
  - Student theses projects
- KT research projects denied because observation of steering committee/staff presentation does not include individual written consent.



# Case Studies 3 & 4 - Issues

- Should individual consent be required for situations where
  - Role of evaluation researcher is transparent?
  - Evaluator has been invited by participants?
  - Where those observed are not the focus of observation? (e.g. flow, not patient focus)
  - Where individual consent discourages participation? Is simply not feasible?



# Case studies 3 & 4 – potential solutions

- Education of reviewers
- Focusing on spirit vs. letter
- “Dividing” activity into research & non-research components



# Case study 5

- Qualitative/KT project proposed as expedited because “low risk”.
- **Issues:** What is risk?
  - Just “medical”?
  - Psychological, reputation, employment, decision-making?



# Beyond the dichotomy...

- What kind of research?
  - Need for broader framework recognizing many kinds of *health services, community health* research
- What about risk? Burden? What kind?
- What are the key ethical issues?
  - Are traditional requirements necessary?
  - What other lens needed?



# Key ethical issues

- Traditional bio-med
- Secondary analysis
- Qualitative research
- Evaluation research
- Knowledge translation
- Protect patient, consent, risk benefit
- Protect privacy, data stewardship
- Confidentiality, risk, community consent
- Staff protection/voice, org accountability
- Confidentiality, power, participation



# Implications

- Information and consent process, forms
- ***Additional*** ethical considerations
  - reflective of issues for each type
- Staff, not just patient, protection
- New era of collaborative research
  - What should come under “ethical review”?



# Conclusion

- Research/QI comparison insufficient
- Reliance on research criteria assuming bio-medical research review paradigm
  - May discourage/prevent knowledge generation
  - May not adequately protect people
  - May use scarce resources inefficiently
- Broader framework needed if we are truly to increase knowledge, protect people



## Contact information

Sarah Bowen, PhD

[sbowen@wrha.mb.ca](mailto:sbowen@wrha.mb.ca)

(204) 926-7127



Winnipeg Regional  
Health Authority  
*Caring for Health*

Office régional de la  
santé de Winnipeg  
*À l'écoute de notre santé*